

Minutes  
Registration Review Workgroup  
Pesticide Program Dialogue Committee  
**February 2, 2004 Meeting**  
Crystal Mall 2, Arlington VA

Participants

EPA: Jay Ellenberger, Susan Lewis, Richard Dumas, Carol Stangel, Philip Ross, Tony Kish, TJ Wyatt, Vivian Prunier

PPDC Workgroup: Cindy Baker (via teleconference), Wally Ewart (via teleconference), Brigid Klein (substituting for Steve Kellner), Therese Murtagh, Julie Spagnoli, Ray McAllister, Janine Rynczak (substituting for Warren Stickle), and Sue Crescenzi

Public attendees: Rebecca Freeman, American Farm Bureau; Mary Beth Polley, Pesticide and Toxic Chemical News, Phil Zahodiakin, Pesticide Insider; Robert M. Sielaty, Wright and Sielaty.

Introduction. Jay Ellenberger described the agenda for the meeting. The group agreed that it would discuss issues one, two and five at today's meeting.

Minutes of January 2, 2004 Teleconference. The draft minutes were amended to add or correct participants' names and affiliations.

Issue One. *What action(s) initiates a pesticide registration review?* Before expending resources in a pesticide's registration review, the Agency would want to know whether registrants intend to support the pesticide and each of its uses. Other stakeholders might want to know this as well. The Agency is seeking advice on options for getting this type of information up-front in a way that is efficient for both the Agency and the public.

Options include:

- Agency publishes schedule. Agency notifies registrants by letter that it has commenced its review. No action required from stakeholders at this point. Stakeholders do not provide input until the results of the review are available.
- Agency publishes schedule. Agency identifies documents that it will evaluate in the review and places this information (i.e., either a list of documents or the documents themselves) in the docket for registrant and stakeholder review.
- Agency publishes schedule. A pesticide's registration review begins when the Agency

receives notification from registrants regarding their intent to support the pesticide's registration review. In their evaluation of this option, stakeholders said that payment of annual maintenance fees is sufficient demonstration of intent to support the registration. Accordingly, submission of additional notification would not be unnecessary.

The workgroup supported the second option. The workgroup discussed the documentation that the Agency might provide under this option. The information might include copies of labels and/or a list of registered uses; the RED or TRED for the pesticide; and copies of the most recent risk assessments for each scientific discipline. There was brief mention of including a list of data requirements for the registered uses of the pesticide and a list of studies that had been submitted, but these ideas were not pursued.

The workgroup acknowledged that the Agency might have to upgrade its information management systems to support this activity.

Issue Two. *Early submission of test data and other information to support a pesticide's registration review.* The Agency wants to receive pertinent information early in the registration review process in order to avoid redoing its risk assessments. Such rework delays completion of the pesticide's review and ties up scarce resources.

Options include:

- Stakeholders take no action until they have the results of the Agency's review.
- When it initiates a registration review, the Agency issues a Data Call-in Notice requiring the submission of any existing information that is pertinent to the pesticide's registration review. This information might include studies that were submitted to foreign governments in support of uses not registered in the US or in response to additional requirements imposed by other governments, risk assessments prepared by other governments, or information on use and usage.
- After the Agency has assembled the information it will review – but before it has evaluated it – convene a “SMART” meeting with stakeholders to discuss the Agency's need for additional information and whether stakeholders possess information responsive to the Agency's needs.
- After the Agency has publically identified the information it has assembled for a pesticide's registration review, registrants and other stakeholders respond by providing a list of studies or other information that is pertinent to the registration review.

Because of the novelty of the last option, workgroup members needed to consult with their constituencies. Questions included: What items belong on such a list? How does a registrant decide whether to list an item? Are there confidentiality or other issues related to releasing such a list?

The workgroup then discussed early submission of stakeholder's information that might pertain to the use and usage of a pesticide. The Agency would like to know – before it conducts a risk assessment – whether actual usage rates are lower than the labeled rates. Stakeholders want to avoid assembling such information until it is reasonable certain that this information is needed to preserve the use of the pesticide. However, if stakeholders see what the Agency will be evaluating in the registration review, they can decide for themselves if additional information should be provided to support a pesticide or a particular use.

USDA could need several years' lead time if it is going to include a particular pesticide in its PDP or NAS programs. Growers also needed a long lead time to identify their issues and get organized.

Issue Five. *What is a registration review decision?* In a pesticide's registration review, the Agency would determine whether a pesticide meets the requirements for registration under FIFRA section 3(c)(5). Additionally, FIFRA section 3(g)(2)(A) stipulates that EPA shall use its authority under FIFRA section 3(c)(2)(B) to require submission of data when such data are necessary for registration review. The workgroup has discussed a number of possible scenarios that might represent the completion of registration review.

The workgroup acknowledged that a DCI for data needed for a risk assessment could not be an endpoint for the registration review. In such cases, completion of the registration review would be deferred until the data are submitted and evaluated. The workgroup considered what a "needs a DCI" determination would be called. The Agency's workgroup had been using the term "interim decision," but it is possible that other terms could be used to characterize such cases. Another concern was that additional issues might arise during while a registration review decision was pending and that these issues might further delay completion a registration review.

Action Items:

- Ray McAllister volunteered to lead the write up of Issue One.
- Cindy Baker, Julie Spagnoli, and Sue Crescenzi to explore the issues relating to having registrants submit bibliographies (an option in Issue Two). Therese Murtagh volunteered to work with them.
- Sue Crescenzi has the lead for writing up Issue Five.
- TJ Wyatt will prepare an e-mail asking workgroup members to consider costs and benefits of the options for each of the three issues.

Schedule for Workgroup Meetings and Teleconferences. The next meeting is scheduled for Tuesday March 2. However, it may be necessary to change the date of this meeting – possibly to the preceding day.

